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EXAMINER

NAJARIAN, LENA

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/002,669	Applicant(s) HARTLAUB, JEROME T.	
	Examiner LENA NAJARIAN	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 27-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-26 and 39-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 6/17/08. Claims 12 and 21 have been amended. Claims 1-11 and 27-38 are withdrawn. Claims 12-26 and 39-48 are rejected.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 12-15, 17-26, 39 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Pilarczyk (4,766,542).

(A) Referring to claim 12, Lebel discloses an implantable drug delivery device for delivering at least one drug to a patient comprising in combination (abstract of Lebel):

(a) at least one reservoir each containing at least one drug (para. 60 of Lebel);

(b) a drug scheduling module for determining whether the drug should be replenished (para. 179 of Lebel); and

(d) a telemetry module providing bi-directional communications with an external device (Fig. 3 of Lebel),

wherein the drug scheduling module receives data about the implantable drug delivery device, wherein the data is drug usage information (para. 179 and para. 180 of Lebel).

Lebel does not disclose an appointment scheduling module automatically initiated by the drug scheduling module, and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device and allowing the appointment scheduling module to schedule the appointment.

Pilarczyk discloses an appointment scheduling module automatically initiated by the drug scheduling module, and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device and allowing the appointment scheduling module to schedule the appointment (col. 1, line 52 – col. 2, line 34 and col. 6, lines 15-55 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

Insofar as the claim recites “selected from the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 13, Lebel discloses wherein the module contacts via the external device at least one entity, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient (para. 134 of Lebel).

Lebel does not expressly disclose an appointment scheduling module.

Pilarczyk discloses an appointment scheduling module (col. 1, line 52 – col. 2, line 34 and col. 6, lines 15-55 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

(C) Referring to claim 14, Lebel discloses the drug scheduling module further receives data (para. 320 of Lebel).

(D) Referring to claim 15, Lebel discloses wherein the drug management instructions is deliver drug to a specified location (para. 204 of Lebel).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(E) Referring to claim 17, Lebel discloses wherein the drug scheduling module includes a drug management algorithm to forecast when a next refill of pump reservoir is required (para. 179, para. 207, and para. 318 of Lebel).

(F) Referring to claim 18, Lebel does not disclose wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

Pilarczyk discloses wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is a pharmacy (col. 1, line 52 – col. 2, line 34 and col. 7, lines 19-54 of Pilarczyk)

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(G) Referring to claims 19 and 20, Lebel discloses wherein the implantable drug delivery device is in communication with a computing device, the computing device operatively coupled to the entity (see Fig. 3 of Lebel).

Lebel does not disclose wherein the computing network is the Internet. However, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a network such as the Internet in order to provide world wide access to the services provided by the system.

(H) Referring to claim 21, Lebel discloses an implantable drug delivery device, comprising (para. 204 and Fig. 3 of Lebel):

(a) a housing (para. 204 and Fig. 3 of Lebel);

(b) a drug reservoir carried in the housing configured to contain a therapeutic substance (para. 204 and Fig. 3 of Lebel);

(c) a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port (para. 204 and Fig. 3 of Lebel);

(d) electronics coupled to the flow control and a power source (para. 204 and Fig. 3 of Lebel);

(e) a telemetry module coupled to the electronics (para. 204 and Fig. 3 of Lebel);

(f) memory coupled to the electronics, the memory containing pump refill criteria and other refill criteria (para. 204, para. 179, para. 186, and Fig. 3 of Lebel);

(g) a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable (para. 204, para. 179, and para. 186 of Lebel);
and,

(h) a refill module coupled to the memory and the electronic, the refill module configured to calculate at least one relationship among the pump refill criteria and monitored pump variables, the refill module configured to decide whether a pump refill activity should be reported, and the refill module configured to activate the telemetry module to report a refill activity, wherein the module is adapted to contact via the telemetry module a physician for the scheduling activity (para. 204, para. 179, para. 186, Fig. 3, para. 132, and para. 134 of Lebel).

Lebel does not expressly disclose the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required and to contact at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient.

Pilarczyk discloses the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required and to contact at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient (col. 1, line 52 – col. 2, line 34 and col. 6, lines 15-55 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for

replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

Insofar as the claim recites “selected from the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(I) Referring to claim 22, Lebel discloses wherein the refill module determines whether an appointment is necessary to perform a pump refill (para. 179 and para. 186 of Lebel).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(J) Referring to claim 23, Lebel discloses wherein the refill module communicates via the telemetry module with an external device (Fig. 3 of Lebel).

(K) Referring to claim 24, Lebel discloses contacting the patient via the telemetry module (para. 134 and Fig. 3 of Lebel).

Lebel does not disclose wherein the scheduling module contacts the patient for the appointment scheduling.

Pilarczyk discloses wherein the scheduling module contacts the patient for the appointment scheduling (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for

replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

(L) Claims 25 and 26 repeat the same limitations of claims 19 and 20, and are therefore rejected for the same reasons given for those claims.

(M) Referring to claim 39, Lebel does not disclose wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled by the drug scheduling module to initiate the automatic scheduling of an appointment.

Pilarczyk discloses wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled by the drug scheduling module to initiate the automatic scheduling of an appointment (col. 1, line 52 – col. 2, line 34 and col. 6, lines 15-55 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

(N) Claims 44 repeats the same limitations as claim 39, and is therefore rejected for the same reasons given above.

4. Claims 40-41 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Pilarczyk (4,766,542), and further in view of Mayer et al. (US 2002/0010597 A1).

(A) Claims 40-41 and 45-46 have not been amended and are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Pilarczyk (4,766,542), and further in view of Akers et al. (6,112,182).

(A) Claim 16 has not been amended and is therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

6. Claims 42-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Pilarczyk (4,766,542), and further in view of Cummings, Jr. et al. (US 6,345,260 B1).

(A) Claims 42-43 and 47-48 have not been amended and are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

Response to Arguments

7. Applicant's arguments with respect to claims 12 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571)

272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./
Examiner, Art Unit 3686
In
10/3/08

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686